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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,987	01/11/2001	Marc De Beuckeleer	514412-2025	2496

7590 10/03/2002

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/758,987	DeBeuckeleer
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 19, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above, claim(s) *1-7, 16-18, 26, and 27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8-15, 19-25, and 28-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group II in Paper No. 8 is acknowledged. An action on the merits of claims 8-15, 19-25, and newly added claims 28-33 follows.

Claim Rejections - 35 USC § 112

Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-15, 19-25 and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to nucleic acid sequences (probes and primers) and kits comprising such sequences that have 80% sequence identity to a sequence comprising part of the flanking sequence of GAT-ZM1 or to nucleotides 286-487 of SEQ ID NO 6, and further to sequences for the identification of elite event GAT-ZM1 in biological samples. The claims are also drawn to sequences amplified by such primers.

With regard to claims which broadly encompass sequences for identifying an elite event GAT-ZM1 as discussed in the 112/2nd paragraph rejections, it is unclear what the term "elite

event GAT-ZM1" corresponds to. The specification defines an event "as an (artificial) genetic locus that, as a result of genetic manipulation, carries a transgene comprising at least one copy of the of a gene of interest. The typical allelic states of an event are the presence of absence of foreign DNA..." (P. 5). The specification further defines "foreign DNA" as "... [foreign DNA] may comprise both recombinant DNA as well as newly introduced, rearranged DNA of the plant..." (P. 4). Thus it is unclear from the definitions in the specification as to whether the term refers to an event, such that many different nucleic acid sequences can define the event, so long as incorporation of the pat gene has occurred in the plant genome, or does the term refer to a specific nucleic acid sequence. If the former is the case, the specification has only taught two sequences, SEQ ID NOS 6 and 10, which are nucleic acid sequences comprising a 5' flanking region, or 3' flanking region, respectively, of GAT-ZM1. As the specification has not taught the sequence of GAT-ZM1, a single nucleic acid sequence which is drawn to a single 5' flanking region of GAT-ZM1, (or a single 3' flanking region) does not correspond to a representative number of nucleic acid sequences by which an "elite event GAT-ZM1" can be defined. If the latter is the case, it is unclear from the recitation in the specification as to what the actual sequence of GAT-ZM1 is.

With regard to claims reciting 80% sequence identity, or to claims reciting the term "essentially similar", as discussed above, it is unclear what the "elite event GAT-ZM1" corresponds to. As this term does not appear to be art recognized, such a sequence can only be identified by a specific SEQ ID NO. The specification appears only to have taught identification

of a single elite event GAT-ZM1, with a nucleic acid sequence consisting of the nucleic acid sequence of nucleotides 286-487 from SEQ ID NO 6. Yet the claims, which are to sequences having "at least 80% identity" with the single sequence taught in the specification, may encompass hundreds of polynucleotides. As discussed below, Applicant's definition of "% identity" is insufficient to provide a skilled artisan with the guidance necessary to clearly define the sequences encompassed by this claim language. Without specific teachings with respect to the methods used to determine "% identity", a skilled artisan could not be expected to identify or make the polynucleotides encompassed by the instant claims. Furthermore, irrespective of how "% identity" is defined, it is clear that by any definition of "% identity", may sequences encompassed by applicant's claims, and particularly those having "at least 80% identity" with fragments of the single sequence taught in the specification, would bear little resemblance to SEQ ID NO 6 such that an elite event GAT-ZM1 could be identified. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify such polynucleotides, other than those described by SEQ ID NO. Furthermore, It is unclear from the recitation as to what degree of similarity or difference can be encompassed by a probe which is "essentially similar" to the nucleic acid sequence of SEQ ID NO 6. As SEQ IDNO 6 is drawn to "a nucleotide sequence comprising a 5' flanking region of GAT-ZM1" and it is further unclear how the term GAT-ZM1 is defined (that is, what is the nucleic acid sequence of GAT-ZM1), it is unclear as to how a nucleic acid sequence is

"essentially similar" to SEQ ID NO 6 because the specification does not define what is "essential" to SEQ ID NO 6.

With respect to claims 28-31, the DNA molecules obtained from amplification using primers with "comprise" 15-20 nucleotides complementary to SEQ ID NO 6 or 10 and a sequence complementary to "the foreign DNA" and to specific primers "comprising" SEQ ID NOS 11 and 12 encompass any DNA molecule that can be associated with any "event" or transformation of SEQ ID NO 1 into corn genome, and is not limited to the elite event described in the specification. Such DNA molecules, as well as molecules comprising SEQ ID NO 6 or 10 (claim 32) encompass nucleic acid sequences of unlimited size which contain undisclosed genomic DNA as well as "foreign" DNA. Further, with respect to claim 33, it is unclear which nucleotides form the "insertion site" within SEQ ID NOS 6 and 10. Such claims encompass a large genus of nucleic acids and the recitation of SEQ ID NOS 6, 10, 11, and 12 are not representative of the large genus of nucleic acids that are encompassed by these claims. Further, with respect to claim 33, it is unclear which nucleotides form the "insertion site" within SEQ ID NOS 6 and 10.

Each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112/1st paragraph. As set forth by the Court in *Vas Cath In. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a clear description of a

representative number of sequences that correspond to "elite event GAT-ZM1", the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Indefinite

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-15, 19-25, 28-31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of "elite event GAT-ZM1" as it is unclear whether this term refers to the incorporation of the pat gene encoding tolerance to phospinothricin, or whether the term refers to an actual DNA sequence. If the latter is the case, it is unclear from the recitation in the specification what the actual full nucleic acid sequence of "elite event GAT-ZM1" is. The recitation of "elite event GAT-ZM1" does not appear to be an art recognized term, clarification is required.

Claims 9-11, 17, 23 and 28 are indefinite in the recitation of "the foreign DNA" as this term lacks antecedent basis. It is unclear from the recitation in the claims and specification as to which sequences constitute "foreign DNA".

Claims 14 and 15 are indefinite in the recitation of "the primer" as this term lacks antecedent basis. It is unclear from the recitation as to which primer is being referred to.

Claim 25 is indefinite in the recitation of "essentially similar" as it is unclear how this term further limits the invention. It is unclear from the recitation as to what degree of similarity or difference can be encompassed by a probe which is "essentially similar" to the nucleic acid sequence of SEQ ID NO 6. Thus the metes and bounds are unclear with regard to the recitation of "essentially similar". As SEQ IDNO 6 is drawn to "a nucleotide sequence comprising a 5' flanking region of GAT-ZM1" and it is further unclear how the term GAT-ZM1 is defined (that is, what is the nucleic acid sequence of GAT-ZM1), it is unclear as to how a nucleic acid sequence is "essentially similar" to SEQ ID NO 6 because the specification does not define what is "essential" to SEQ ID NO 6.

Claim 33 lacks sufficient antecedent basis for the recitation of "the insertion site".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number X20316 (in WO9858943 - June 18, 1998) or in the alternative by Accession number 020951 (in EP-469273 - February 5, 1992).

The claims are drawn to a nucleic acids having a sequence which can recognize the 5' or 3' flanking region of GAT-ZM1 or to nucleic acids having at least 80% sequence identity with SEQ ID. NOS 6 or 10. As the claim language in claim 12 is drawn to the term "having", and since the specification has not defined whether this term corresponds to 'open' or 'closed' language, the term having has been interpreted in it's broadest sense, thus the claims encompass a nucleic acid 'comprising" a sequence that can recognize the 5' or 3' flanking region of GAT-ZM1 or to nucleic acids comprising a sequence having at least 80% sequence identity with SEQ id. NOS 6 or 10. Accession number X20316 teaches a sequence which has 94.4 % sequence identity with a portion of SEQ ID NO 6, and Accession number 020951 teaches a sequence which has 99.4 % sequence identity with a portion of SEQ ID NO 10.

8. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by accession number AR040951 (from US Patent 5,811,238, issued 9/22/98).

As the claim language in claim 15 is drawn to the term "having", and since the specification has not defined whether this term corresponds to 'open' or 'closed' language, the term having has been interpreted in it's broadest sense, thus the claims encompass a nucleic acid 'comprising" the sequence of SEQ ID NO 12. Accession number AR040951 teaches an

oligonucleotide composed of 23 nucleotides (SEQ ID NO 50 from the patent) for which nucleotides 2-23 are identical to SEQ ID NO 12.

9. Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by accession number E00019 (9/29/1997).

Accession number E00019 teaches a sequence which is identical to sequences 57-202 of SEQ ID NO 6. It is unclear from the teachings in the specification or the recitation in the claim as to what regions of SEQ ID NO 6 comprise "the 5' flanking sequence of GAT ZM1" and "the sequence of the foreign DNA", therefore, the claims have been broadly interpreted to encompass accession number E00019.

10. Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number A36368 (March 5, 1997).

Accession number A36368 teaches a sequence of 83 nucleotides which is identical to nucleotides 344 to 426 of SEQ ID NO 6. It is unclear from the teachings in the specification or the recitation in the claim as to what regions of SEQ ID NO 6 comprise "the 5' flanking sequence of GAT ZM1" and "the sequence of the foreign DNA", therefore, the claims have been broadly interpreted to encompass accession number A36368.

11. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by DeBlock et al (The EMBO Journal, 1987, vol. 6, pp 2513-2518).

As discussed previously, it is unclear as to what the term "elite event GAT-ZM1" corresponds to, therefore, the claims have been interpreted to encompass detecting the incorporation of the pat gene into a plant. DeBlock teaches that phosphinothricin is a potent inhibitor of glutamine synthetase in plants an si used as a non-selective herbicide (see abstract). DeBlock teaches the construction of a chimeric vector comprising the bar gene for transformation of plants with resistance to phosphinothricin and further teaches that the PAT gene was used as a selectable marker for protoplast cocultivation (see p. 2513, col. 2). DeBlock teaches the transformation of tobacco, potato, and tomato plants to yield plants fully resistant to herbicides comprising phosphinothricin (see p. 2514). DeBlock teaches identification of PAT in transgenic plants (elite event GAT-ZM1) using Southern blotting (see p. 2515). DeBlock further teaches that seven transgenic plants were analyzed and were found to produce normal amounts of viable seed (p 2515, col. 1).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 8-9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBlock et al. in view of Ahern (The Scientist, July 24, 1995; vol: 9, pages 1-5: website-www.the-scientist.library.upenn.edu)..

As discussed previously, it is unclear as to what the term "elite event GAT-ZM1" corresponds to, therefore, the claims have been interpreted to encompass detecting the incorporation of the pat gene into a plant. DeBlock teaches that phosphinothricin is a potent inhibitor of glutamine synthetase in plants an si used as a non-selective herbicide (see abstract). DeBlock teaches the construction of a chimeric vector comprising the bar gene for transformation of plants with resistance to phosphinothricin and further teaches that the PAT gene was used as a selectable marker for protoplast cocultivation (see p. 2513, col. 2). DeBlock teaches the transformation of tobacco, potato, and tomato plants to yield plants fully resistant to herbicides comprising phosphinothricin (see p. 2514). DeBlock teaches identification of PAT in transgenic plants (elite event GAT-ZM1) using Southern blotting (see p. 2515). DeBlock further teaches that seven transgenic plants were analyzed and were found to produce normal amounts of viable seed (p 2515, col. 1).

Claims 8-9 and 19 are drawn to kits comprising a specific probe comprising a sequence which hybridizes to a specific region of GAT -ZM1. The pat gene is located within the GAT-ZM1 region, therefore a probe that hybridizes to the pat gene is encompassed by the claim language. DeBlock teaches identification of PAT in transgenic plants (elite event GAT-ZM1)

using Southern blotting (see p. 2515). Although DeBlock does not teach sequences in kit format, Ahern teaches that kits with premade biochemicals and reagents off scientists the opportunity to better manage their time (see p. 4, lines 1-2). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged nucleotides according to DeBlock in kit format as taught by Ahern for the purpose of providing preweighed, premeasured reagents which would save researchers time in biochemical assays.

14. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over accession number E00019 (9/29/1997) or in the alternative Accession number A36368 (March 5, 1997), each in view of Ahern (The Scientist, July 24, 1995; vol: 9, pages 1-5: website- www.the-scientist.library.upenn.edu).

Accession number E00019 teaches a sequence which is identical to sequences 57-202 of SEQ ID NO 6 and Accession number A36368 teaches a sequence of 83 nucleotides which is identical to nucleotides 344 to 426 of SEQ ID NO 6. It is unclear from the teachings in the specification or the recitation in the claim as to what regions of SEQ ID NO 6 comprise "the 5' flanking sequence of GAT ZM1" and "the sequence of the foreign DNA", therefore, the claims have been broadly interpreted to encompass accession number A36368 or E00019. Although the accession numbers do not teach the sequences in kit format, Ahern teaches that kits with premade biochemicals and reagents off scientists the opportunity to better manage their time (see p. 4, lines 1-2). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at

the time the invention was made to have packaged nucleotides as taught in accession numbers A36368 or E00019 in kit format as taught by Ahern for the purpose of providing preweighed, premeasured reagents which would save researchers time in biochemical assays

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 8-15, 19-25, and 32-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 and 13 of U.S. Patent No. 6,395,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of the '485 patent are coextensive in scope in that they are drawn to the same nucleic acid sequences, or the sequences of claims of the instant invention encompass the sequences of claims 7-10 and 13 of the '485 patent.

Conclusion

17. No claims are allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
9/30/02